REMARKS

The above amendments with the following remarks is submitted to be fully responsive to the Official Action of May 24, 2004. Reconsideration of this application in light of the amendments and remarks to follow is respectfully requested.

The disclosure stands objected to since the drawings fail to include reference numeral 2 and 10. In response, a revised sheet 1 of the drawings is hereby provided with changes to Figures 1 and 2 adding reference numerals 2 and 10. Approval of the drawings and withdraw this rejection is respectfully requested.

Claims 1-4, 7-10, 13 and 16 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner has objected to the use of the word "connectable" in claim 1 and recommended replacement with the word "connected". In response, claim 1 has been amended to adopt the Examiner's suggestion. Therefore, it is respectfully requested that this rejection be withdrawn.

Claims 9, 11, 12, 14, 15, 17 and 18 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. (Please note that in order to reduce the issues for appeal claim 9 has been amended to use similar language of the external valve as set forth in claim 12.)

The Examiner contends that the specification and drawings are so unclear as to how the external proximal valve is structured and how it is connected to the proximal ring 6 that a person with ordinary skill in the art would not be enabled to make and/or use the invention. However, Applicants contend that the specification and drawings clearly teach a person with ordinary skill in the art how to make and/or use the claimed invention for the following reasons. First, the original specification specifically recites that the self-sealing valves 18 and 28 may be equally used as external proximal valves or as internal distal valves, see at least Figures 6, 7, and paragraphs [0025], [0028]. Therefore, the structure of the external proximal valve is clearly taught. That is, the external proximal valve shown in Fig. 7 is attached adjacent to sleeve 4 in a similar manner to the internal distal valve shown in Figures 1-6. As taught by the specification, the external proximal valve is formed on a portion of the sleeve 4

extending from proximal ring 6 just as the internal distal valve shown in Figures 1-6 is formed on a portion of the sleeve 4 extending form distal ring 5. A person with ordinary skill in the art would understand based on the specification and drawings that a portion of sleeve 4 extends outwardly from proximal ring 6 while another portion of sleeve 4 wraps around proximal ring 6, see Examiner's statement "It would have been obvious to include a seal on the Crook device so that it too would have this advantage." Such a statement by the Examiner, along with the teachings of the specification discussed above, constitute a *prima facie* admission that the claims 9, 11, 12, 14, 15, 17 and 18 are in-fact enabled.

The Applicants continue to assert that a person of ordinary skill in the art would understand that sleeve 4 can extend above proximal ring 6 just as it extends below the proximal ring 6 and extend upwardly to accommodate the mounting of the external proximal valve 18 based on the specification. A person of ordinary skill in the art would understand that sleeve 4 may extend in both the direction of the proximal ring and outwardly to provide mounting of the external proximal valve since it is well known to form sleeves in a manner which allows different portions of the sleeve to extend in different directions for attachment of other components, as shown by the following patent documents:

U.S. Patent 5,640,977 (see Figure 2, elements, 13, 18b)
WO99/25268 (see Figure 8, elements 85, 80)
WO95/07056 (see Figure 3, elements 23,2)
WO01/08581 (see Figure 9, element 158, 152, Figure 10)

Thus, a person with ordinary skill in the art would understand that sleeve 4 could extend both around proximal ring 6 and a portion of the sleeve could also extend upwardly for mounting of the external proximal valve. Thus, it is believed that the specification, drawings and the knowledge of the person of ordinary of skill in the art is such that one skilled in the art would be able to make and/or use the invention as claimed.

Finally, the Examiner's setting forth a rejection under § 112 (first paragraph-enablement) and § 103, in which the Examiner asserts that a particular feature lacks enablement while at the same time stating that the same feature would have been obvious to one of ordinary skill in the prior art, constitutes an improper "squeeze". As

can be seen from the attached USPTO training presentation entitled "The Squeeze", regarding combined "§ 112 (first paragraph-enablement) and § 103" rejections, the presentation clearly notes that such combination rejections (see for example slides 6, 10, 15) are reserved for the most unusual situations where the claimed invention scope exceeds that of all the prior art, e.g., such as cures for all cancers. The Examiner's use of the "§ 112/§ 103 squeeze" in the instant final Office Action is inconsistent with the guidelines established by the USPTO's "The Squeeze" and further at MPEP Chapter 2164.04 regarding setting forth a *prima facie* case of lack of enablement.

Accordingly, since the § 112(1)-enablement rejections is improper in its analysis and understanding of the prior art at the time of the invention and the Applicants' disclosure and since the § 112(1)-enablement rejection is not consistent with the USPTO procedures for setting forth a proper "§ 112(1)-enablement/§ 103 rejection, reconsideration and withdrawal of the rejection of claims 9, 11, 12, 14, 15, 17 and 18 under 35 U.S.C. 112, first paragraph, is in order and respectfully requested.

Claim 3 also stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for a double citation of the sealing means. In order to further reduce the issues for appeal, claim 3 has been amended to clarify that the sealing means of claim 1 includes a self-sealing valve mounted on the sleeve. Thus claim 3 further restricts the sealing means recited in claim 1 and does not now result in a double recitation of the same part. Accordingly, it is respectfully requested that this rejection has been overcome.

Claims 1-4 and 7-18 stand rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bonadio (WO 95/22289). However, in response, Applicants contend that Bonadio does not render the present invention as recited in independent claims 1, 11 and 12 anticipated or obvious for the following reasons.

Bonadio discloses a body cavity engagement means, a sleeve and a sealing means 102. The Examiner states that Bonadio further includes a proximal ring 44 which if pulled upwardly would inherently cause the sleeve to apply outward pressure against the patient's body to retract the incision. However, this statement by the Examiner is simply not factually accurate and completely contrary to the teachings of

Bonadio in that upward movement of proximal ring or flange 44 is not explicitly or implicitly taught by Bonadio and, further, would not cause the sleeve to apply outward pressure against the patient's body to retract the incision. Bonadio nowhere suggests such an interpretation and, as a practical matter, upward movement of flange 44 would merely result in the movement of the sleeve upwardly through the incision and out of the cavity and cause the bands 55 to abut the inner wall of the patient's body. The structure of the Bonadio design simply does not permit an outward pressure against the patient's body sufficient to retract the incision, see page 22, line 2-7, where it is stated that inflation of the cavity results in leakage of gas between the incision and the sleeve. Further, Bonadio clearly teaches that the upper seal, e.g., 44, provides the sealing necessary such as by being adhesively attached to the skin, see page 5, lines 19-23, page 12, lines 5-18, and page 21, lines 26-33). Such a teaching would not implicitly (inherently) teach one of ordinary skill in the art that "pulling" as stated would be intended or "necessarily present" as is required for "inherency" to exist, see the guidelines set forth in MPEP Chapter 2112.

It is specifically requested that the Examiner, in the next Office Action, provide a detailed reasoning and/or technical showing supporting the "inherency" of the sleeve of Bonadio to be pulled up and to draw the sleeve outwardly against the incision, as is required by MPEP 2112. Such an explanation will greatly reduce the issues for appeal by clearly defining on the technical capabilities of Bonadio from the Examiner's perspective and permit the Applicants to provide a precise traversal as appropriate.

Further, as the Examiner is aware MPEP Chapter 2143.01 clearly states that a proposed modification of a reference to include a feature or functionality which is contrary to the purpose or function stated in a prior art reference and/or which would render the teachings of the prior art reference unsatisfactory for its intended purpose does not provide a proper suggestion/motivation to make the proposed change. Since Bonadio does not explicitly state (or remotely suggest) such a retraction and nowhere discusses any form of retraction by (upward) movement of the flange 44 (to contrary flange 44 remains in place on the skin to form a seal), the "inherent" movement of the flange (such as during positioning of the flange adjacent the incision) would not as a

technical and practical matter result in outward pressure to retract or open the incision. Bonadio is simply an access port device for permitting access to a patient's body cavity but does not function as a retractor for prying an incision open using outward pressure as presently claimed. Thus Bonadio does not teach or even remotely suggest an inherent capability of a sleeve which is adjustable by the positioning of a proximal ring so that the positioning of the proximal ring retracts the sleeve to cause the sleeve to apply outward pressure against the patient's body to retract the incision to define an access port and create a seal between the incision and sleeve as specifically recited in independent claim 1.

Nor does Bonadio anywhere teach or suggest the sleeve having an adjustable length that shortens (claim 11) or an adjustment means for adjusting the length of a sleeve (claim 12) to cause the sleeve to apply outward pressure against the patient's body sufficient to retract the incision. Bonadio is completely devoid of any teaching of an "adjustable" length sleeve. Moreover, there is certainly no suggestion or motivation in Bonadio to modify the Bonadio teaching so as to provide a sleeve which is adjustable by the positioning of the proximal ring so as to retract the sleeve to cause the sleeve to apply outward pressure against the patient's body to retract the incision. Nor is there any suggestion or motivation to modify the Bonadio teaching to include a sleeve having an adjustable length that shortens to cause the sleeve to apply outward pressure to retract the incision.

Moreover, as to claims 13-15, the Examiner asserts that the sealing means is a feature of means 102 in Bonadio yet then states that the arcuate bands 55 in Bonadio correspond to the elasticized filaments. However, claims 13-15 specifically require the sealing means (claim 13), or the external or internal sealing valve (claims 14 and 15), to be a self-sealing valve formed of elasticized filaments. Bonadio does not state or even remotely suggest that sealing means 102 includes elasticized filaments. Therefore, Bonadio does not anticipate or render obvious the present invention as recited in dependent claims 13-15. Likewise, claims 16-18 are not anticipated nor rendered obvious by Bonadio since the sealing means 102 in Bonadio does not include a self-sealing spring valve much less a tensioned member mounted on the sleeve as the spring valve. Thus, dependent claims 16-18 are also allowable over Bonadio.

In summary, the Bonadio reference simply does not (explicitly or implicitly) teach, disclose, suggest or otherwise motivate a person of ordinary skill in the art to incorporate the features of the invention as claimed in independent claims 1, 11 and 12. Importantly, the Bonadio access device does not and could not inherently operate in the manner described by the Examiner to retract the incision, and, further, the teachings therein are in fact contrary to the device of claims 1, 11 and 12. Upward movement (as suggested by the Examiner) of flange 44 will not apply outward pressure against the patient's body to retract the incision and the flat adhesive surface provided on flange 44 fundamentally foregoes rotation of the flange while maintaining the adhesive surface exposed for connection as required by the Bonadio teaching. Bonadio simply fails to teach a sleeve which functions in any manner to retract on the sides of an incision, and certainly fails to teach the manner of retraction recited in independent claims 1, 11 and 12 of the present application. Thus, Bonadio neither anticipates nor renders obvious the present invention as recited in independent claims 1, 11 and 12 (or dependent claims 2-4, 7-10, 13-18).

Accordingly, reconsideration and withdrawal of the rejection of independent claims 1-4, 7-18 under 35 U.S.C. 102(b) or under 35 U.S.C. 103(a) is in order and respectfully requested. Please note that dependent claims 14, 15, 17 and 18 are amended to reduce the issues for appeal by merely correcting an antecedent deficiency.

Claims 1-4 and 7-18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Crook '550 in view of Bonadio. Applicants contend that the combination of Crook and Bonadio fails to render the present invention, as recited in independent claims 1, 11 and 12, obvious for the following reasons.

The present invention as recited in independent claims 1, 11 and 12 provides a surgical access device which permits effective retraction of an incision by adjusting a sleeve to provide outward pressure to a patient's body at the incision to define an access port in combination with a sealing means or sealing valve which prevents substantial leakage of gas from the cavity on inflation when in an inoperative position and formed to mould about a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position. Admittedly, the Crook reference discloses a surgical retractor incorporating a sleeve. However, Crook fails to disclose

any form or means for sealing around a hand or instrument extending through the retractor; while Bonadio does not suggest a retractor for applying outward pressure to the sides of the incision to retract the incision. Note the structure of Bonadio, in order to form a proper seal requires that the flange 44, which is part of the external sealing sleeve 40, remain fixed adjacent the patient's skin in the area of the incision. The Applicants assert that to combine the teachings of Bonadio with those of Crock would require significant reengineering of the teachings of Bonadio sealing structure to accommodate the roll down sleeve structure of Crook so as to remain fixed adjacent the patient skin.

The Examiner states that it would be obvious to include a seal on the Crook device so that it would have an advantage of insuring the gas does not escape the patient. However, the Examiner is merely stating an advantage of the Bonadio valve but such a statement does not provide motivation for combining the valve with a retraction device. Both Crook and Bonadio each have independent advantages in that Crook advantageously retracts an incision while Bonadio advantageously provides a sealing means in the access port. It is quite apparent that using hindsight, with full knowledge of Applicants' invention, the Examiner is plucking these two distinct teachings from the vast prior art to claim obviousness. However, neither Bonadio nor Crook suggested in any way the application of one device to the other. Without some motivation to actually combine the references, a person of ordinary skill in the art would not turn to these distinct teachings and combine the retractor of Crook and the sealing means of Bonadio. This lack of motivation is especially evident in view of the fact that Bonadio provides an access port through the incision without any mention whatsoever of some form of retraction to seal the sleeve to the sides of the incision. Moreover, Bonadio certainly fails to suggest that some form of outward pressure type retraction is desirable (much less a sleeve that is adjustable or has an adjustable length to apply outward pressure against the patient's body as presently claimed). Thus, it is respectfully requested that the combination of Crook and Bonadio does not render the present invention as recited in independent claims 1, 11 and 12 obvious.

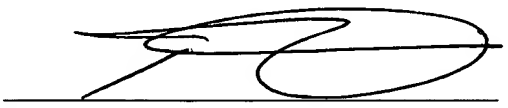
Accordingly, reconsideration and withdrawal of the rejection of claims 1-4 and 7-18 under 35 U.S.C. 103(a) is in order and respectfully requested.

Finally, it is noted that the submission of the four prior art reference discussed above, are for the purpose showing the operativeness of a claimed feature and are accordingly not subject to the requirements of 37 C.F.R. § 1.97 & § 1.98, as noted in MPEP Chapter 609 @ (1)(C)(3). **However, for the Examiner's convenience a completed PTO-1449A is provided herewith, and it is respectfully requested that the Examiner indicate consideration of the above provided references by providing, in the next Office Action, an initialed copy of the PTO-1449A form.**

In view of the foregoing, it is submitted that the present application is in condition for allowance and a notice to that effect is respectfully requested. However, if the Examiner deems that any issue remains after considering this response, he is invited to call the undersigned to expedite the prosecution and work out any such issue by telephone.

Lastly, it is noted that a separate Extension of Time Petition (two months) accompanies this response along with an authorization to charge the requisite extension of time fee to Deposit Account No. 19-2380 (741890-20). However, should that petition become separated from this response, then this response should be construed as containing such a petition. Likewise, any overage or shortage in the required payment should be applied to Deposit Account No. 19-2380 (741890-20).

Respectfully submitted,



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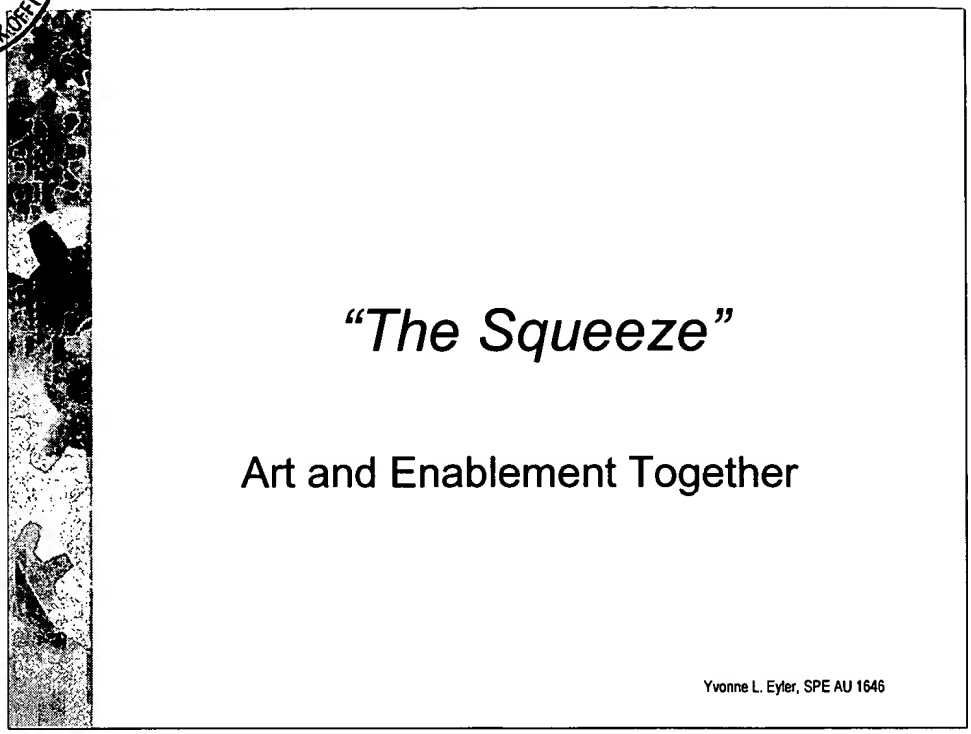
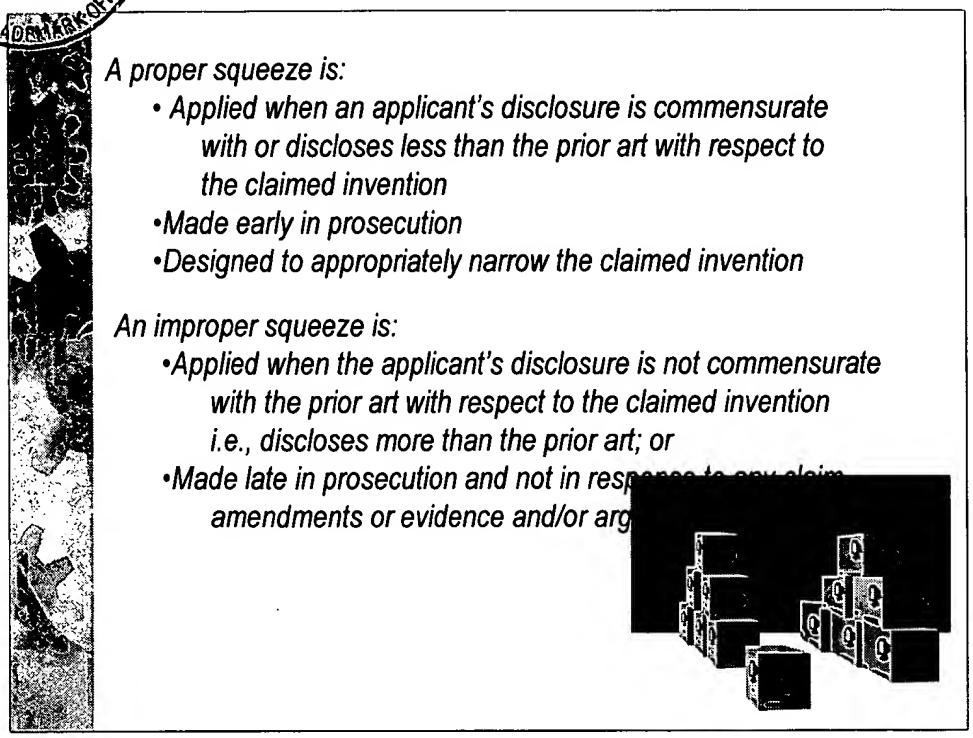
Amendments to the Drawings:

The attached sheet of drawings includes changes to Figs. 1 and 2. This sheet, which includes Figs. 1, 2 and 7, replaces the previous replacement sheet including Figs. 1, 2 and 7. Figure 1 has been amended to show reference numeral 10 identifying the fixing means discussed in the specification and claims and Figure 2 has been amended to show reference numeral 2 - for the internal (abdominal) cavity discussed in the specification at least at paragraph [0015] - and numeral 10.



When is it appropriate to apply both an art rejection and an enablement rejection?



Today I'll talk about examples of both improper and proper squeeze, beginning with improper combinations

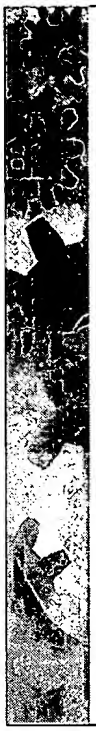
Lack of Enablement and Art-

Specification Discloses More Than Prior Art

- Claim 1: A method of treating ORANGE syndrome comprising administering to a patient an antibody that decreases the level of FL polypeptides associated with fluid retention.

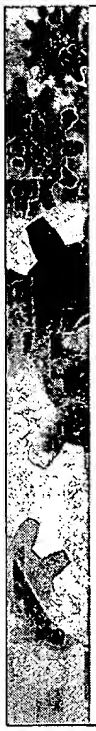
The Specification Discloses

- Increased levels of FL polypeptides in ORANGE patients
- Cells overexpressing FL *in vitro* show increased permeability
- Mice overexpressing FL show increased fluid retention which is alleviated by administration of antibodies to FL.



The Prior Art Teaches:

- Increased levels of FL polypeptide is diagnostic of ORANGE syndrome.



An Improper "Squeeze"

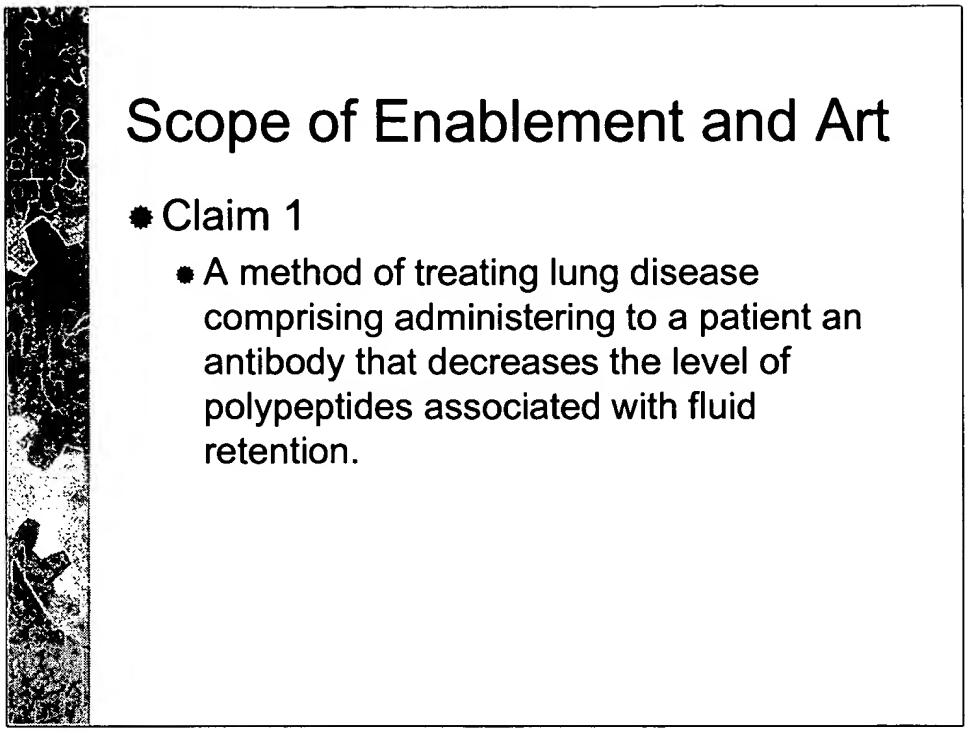
- The examiner rejects claim 1 under 35 U.S.C 112 first paragraph because no working examples of reduction of fluid retention in ORANGE patients are present and further questions the applicability of mouse models in general.
- The examiner also rejects claim 1 under 35 U.S.C. 103 over the art, stating that it would be obvious to administer antibodies to reduce the levels of FL polypeptide in ORANGE patients.

These rejections are examples of inconsistent rejections that box applicant in inappropriately. The invention is simultaneously rejected as not enabled and obvious when there are clear differences between the teachings of the specification and the prior art.

Make it clear that;

if the examiner can support a prima facie case of lack of enablement, an art rejection would be inappropriate because the reference, which is less comprehensive than the disclosure, does not provide an enabling disclosure.

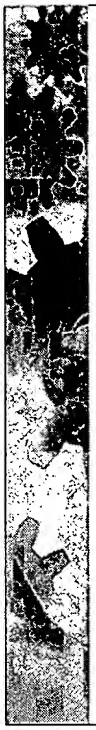
if the reference is sufficient to establish a prima facie case of obviousness (and thus provides an enabling disclosure, considered alone or in combination with the knowledge in the prior art), then the application provides an enabling disclosure.



Now lets look at some examples of a proper squeeze.

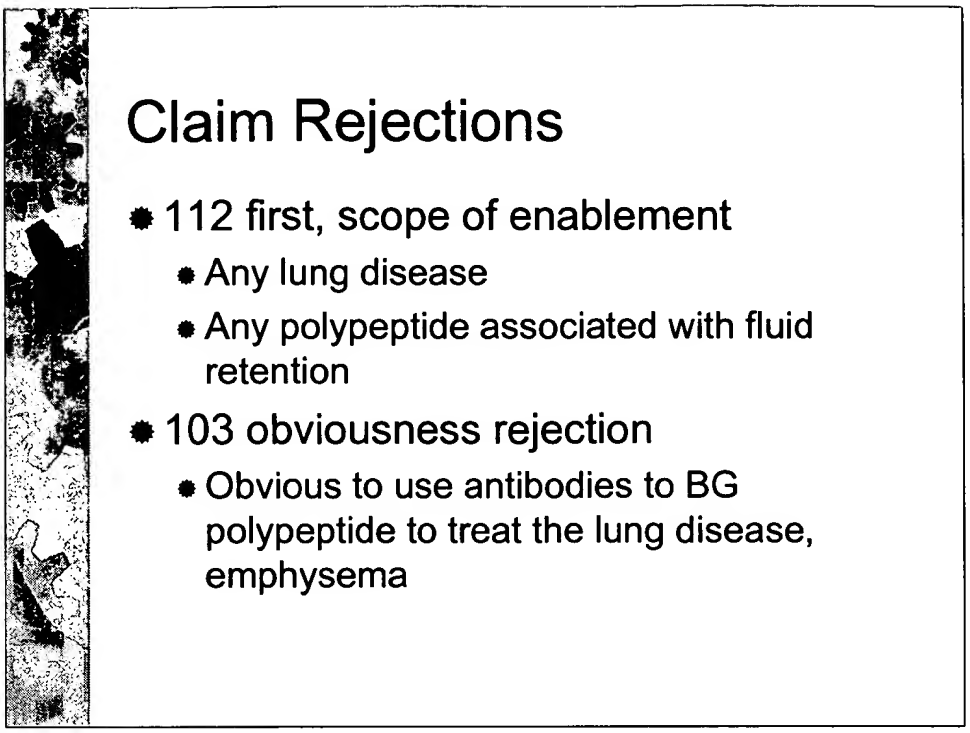
The Specification Discloses

- Increased levels of a novel TP polypeptide (SEQ ID NO: 2) are associated with rockin' pneumonia virus and correlative with fluid retention in the lungs of pneumonia patients.
- Administration of antibodies to SEQ ID NO: 2 to pneumonia patients decreased viral load and fluid retention.



The Prior Art Teaches:

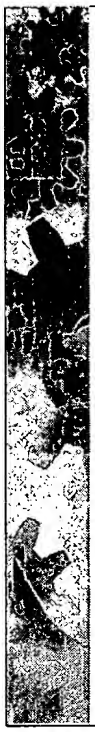
- Polypeptide BG is elevated in emphysema and increases fluid levels in the lungs of emphysema patients.
- Administration of antibodies to BG polypeptide decreases permeability and fluid leakage in cell from emphysema patients.
- Suggests that antibodies to BG may be useful in treating emphysema.



The specifiation does not enable treatment of lung diseases other than rockin' pneumonia and reduction of any polypeptide other than TP

The prior art enables treatment of emphysema by reduction of a polypeptide, BG

Therefore, 2 diseases treatments are clearly enabled, rockin' pneumonia by reduction of TP and emphysema by reduction of BG



Narrower Claim

- A method of treating rockin' pneumonia comprising administering to a patient an antibody that decreases the level of TP polypeptides associated with fluid retention.

The specification fully supports this claim

The prior art does not teach or suggest this claim

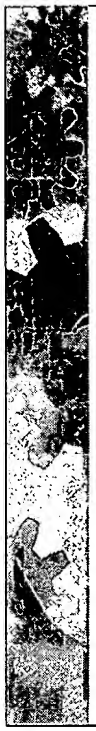
Lack of Enablement and Art-

Specification Commensurate with Prior Art

- Claim 1: A method of treating depression comprising administering agent O.

The Specification Discloses

- The specification has no working examples
- The specification suggests that agent O may be useful in treating depression because it inhibits a polypeptide Q whose level is elevated in some depressed patients.



The Prior Art Teaches:

- Agent O inhibits polypeptide Q *in vitro*
- Polypeptide Q is elevated in some depressed patients
- The prior art hypothesizes that Agent O may be useful in treating depression because it inhibits polypeptide Q
- The prior art provides no data.

Enablement and/or Art?

- In circumstances such as this, where the specification does not appear to add anything not taught by the prior art, the examiner may not have sufficient evidence to determine which rejection is more appropriate, i.e., the art rejection or the enablement rejection. If the specification is enabling, so is the prior art reference, and vice versa.

BOTH Enablement and Art

- Based on the limited evidence, the examiner need not choose the more correct rejection as the result is the same in either instance- the claims are unpatentable.
- The burden is thus placed on applicant to point out how the teachings of the specification go beyond those of the prior art.
- Compact prosecution is served if the examiner makes both rejections in the first instance.

Compact prosecution is served because if only the prior art rejection were made, if applicant can show that the reference is not enabling and is based on an "obvious to try" standard, then the examiner would be in the position of having to drop the art rejection, only to reopen prosecution to make the enablement rejection and give applicant the opportunity to point out how the teachings of the specification go beyond those of the prior art...and vice versa.

Questions?